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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm.1061
Rockville, MD20852
USA

Comments submitted by the Swiss Government on the *Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (PL107-188)*

Dear Sir or Madam

Through the Swiss Embassy in Washington we have learned that FDA will propose and issue regulations on the implementation of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (PL107-188), which was signed into law by the U.S. President on June 12, 2002. The Swiss authorities have also been provided with background information on the issue as well as your request for initial comments.

Since the new regulations may have a significant impact on international trade in food, Switzerland considers it important to submit initial comments on the provisions in Title III, Subtitle A (Protection of Food Supply) at this early stage. It is our understanding that based on the comments received, the FDA will draft and publish proposed regulations by the end of this calendar year, offering a subsequent 60-day comment period and will thus notify the proposed regulations under the appropriate WTO Agreements.

General Observations

As outlined above, Switzerland is concerned that the new regulations may have a significant impact on international trade in food. Acknowledging that the WTO provisions allow countries to take measures necessary to protect human, animal or plant life or health, we would like to stress the importance of these measures being consistent with the fundamental principle of non-discrimination and of them not constituting any disguised restriction to international trade. Furthermore, when taking measures which bear the potential of negative interference with trade, care should be taken to choose the least trade restrictive option available, taking into account the risks non-fulfilment would create.

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Subtitle A – Protection of Food Supply

Sec. 305 Registration of Food Facilities

This section requires that for foreign food facilities registration must include the name of the U.S. agent for the respective facility. We are wondering whether it is a new requirement to have an U.S. agent or whether this provision has been part of the food import requirements already.

Registrants will have to notify the Secretary in a timely manner of any changes to the registration information. This requirement implies that the registration will be valid until withdrawn by the registrant, a concept that we would support.

The definition of facility includes factories, warehouses or establishments of an importer that manufactures, processes, packs or holds food. With respect to the term “warehouse” we are concerned that this term might be too inclusive. We, therefore, suggest that only independent warehouses be subject to the registration requirement but not warehouses which are part of a factory or another establishment that is subject to registration.

Furthermore, Section 305 authorizes the Secretary to provide for and to encourage the use of electronic methods of registration. We would strongly support an efficient registration system which uses electronic methods of registration. Considering that all changes to the information must be notified to the Secretary in due course, on-line registration and the possibility for on-line update of registered information would reduce the administrative burden on both sides. With respect to the new registration requirement, we are of the opinion that all necessary registration forms as well as the rules on how to complete the forms should be made available in the languages of the trading partners.

Section 305 is supposed to amend Section 301 to make failure to register a prohibited act. Considering that any food shipment, which has not been registered will be denied entry until registration has been completed, we are of the opinion that failure to register should not be subject to additional sanction.

Sec. 306 Maintenance and Inspection of Records for Foods

This section requires record keeping for facilities. It is our understanding that this record keeping requirement would be limited to information necessary to determine the immediate previous sources and the immediate subsequent recipients of food. With respect to foreign facilities should be noted that the registration requirement is limited to those who manufacture, process, pack or hold food if food from such facility is exported to the U.S. without further processing or packaging outside the U.S. Consequently the “traceability system” may not use the registration number of facilities as a basis for the record keeping.



When there is a reasonable belief that an article of food is adulterated and hence presents a threat of serious adverse health consequences or death to humans or animals, the Secretary shall be authorised to have access to certain records. While we understand that this provision does not cause any problem on national level, we would like to draw attention to the fact that government acts executed by foreign authorities on Swiss territory constitute a violation of sovereignty and are, therefore, prohibited. Access to records of Swiss facilities would require administrative assistance by Swiss authorities.

With regard to the information which has to be disclosed to authorities we would like to stress the importance of restricting information requests to data which are indispensable for the specific investigation. Confidential business information such as recipes and know-how relating to manufacturing or processing or any other information that is covered by the obligation of professional secrecy should at no times be subject to a disclosure requirement.

Sec. 307 Prior Notice of Imported Food Shipments

With regard to the requirement to provide prior notification for imported food shipments, Switzerland questions the contribution of this requirement to the stated food safety objective. Since all facilities, whether exporting or importing to the U.S., are subject to registration it seems doubtful to us that this prior notice adds any information on the imported food which would be necessary to ensure the safety of the shipments or facilitate product recalls. In our view this requirement constitutes a disproportionate administrative burden, which in addition, is being applied unequally to foreign and domestic facilities.

With respect to the information that must be included in the prior notice of food shipments we would like to note that since the record keeping for registered facilities requires product tracing one step forward and one step backward, some of the required information (i.e. grower) may not be available. With respect to the requirement to indicate the country of origin we were wondering whether this requirement would take up the country of origin concept as used for customs matters or would instead adopt the "country of origin" provisions of the Codex Alimentarius General Standard on Food Labelling¹.

With regard to the practical implementation of the "prior notice" requirement Switzerland fears that administrative procedures would subject admission of the goods to unnecessary delays. Since a number of foodstuffs are perishable such delays would seriously affect imports.

A further requirement states that if prior notice is not provided, the articles shall be refused admission. With respect to this provision, we are afraid that the decision to grant admission will be based on the fact that the "prior notice" has been received by the U.S. authorities. This

¹ CODEX STAN 1-1985 (REV.1-1991)



means that the risk of failure in transmission will be born by the exporting facility, which in our view once more adds a burden to foreign facilities which domestic facilities do not have.

Sec. 303 Administrative Detention

Detention may be ordered if there is credible evidence or information indicating that the article presents a threat of serious adverse health consequences or death to humans or animals. Switzerland is interested in the exact criteria for such judgement and believes that the evidence/information on which the detention decision is taken, will have to be disclosed to the exporting facility since this information is essential for any appeal procedure.

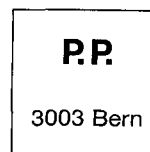
The Swiss authorities would like to thank the FDA for giving due consideration to its comments and to the potential impact of the new regulations on international trade in food in general. Please do not hesitate to contact us if you have any questions. May we kindly ask you to keep us informed with respect to the further procedure on this issue and to provide us with the draft proposal as soon as it is available?

Yours sincerely,

State Secretariat for Economic Affairs
Sectoral Policy Issues

Heinz Hertig
Head Non-tariff Measures Division

copy: - Swiss Embassy, Washington
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